K980334

APR 27 1998

510(K) SUMMARY

1. SUBMITTER:

Innovasive Devices, Inc.
734 Forest St.
Marlborough, MA 01752
Telephone: 508-460-8229

Contact: Stephen M. Page, Manager of Regulatory Affairs
Date Prepared: January 26, 1998

2. DEVICE:

Innovasive 10mm LinX HT
Classification Name: Single/multiple component bone fixation appliances and accessories.
Trade Name: Innovasive Devices 10mm LinX HT Ligament Fastener

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for the Innovasive Devices 10mm LinX HT Ligament Fastener was the 8mm LinX HT Ligament Fastener marketed by Innovasive Devices, Marlborough, MA.

4. DEVICE DESCRIPTION:

The Innovasive 10mm LinX HT utilizes a **central pin** placed inside an **outer sleeve** resulting in the expansion of the outer sleeve and the ultimate fixation of the device into bone. The Innovasive Devices 10mm LinX HT will be offered in two sizes, 10mm outside diameter x 40mm length, and 10mm outside diameter x 55mm length.

The **outer sleeve** has threads on its exterior to hold to the bone and a central ID designed to accept the pin component.

The **central pin** has ribs along its length designed to expand the outer sleeve as it is placed down the sleeve inside diameter. The front of the pin has a through-hole to accept a piece of suture to guide the pin into the sleeve during the deployment of the device. The suture is then removed and discarded.

5. INTENDED USE:

The 10mm LinX HT is intended for use in the fixation of ligament and tendon grafts in cruciate ligament reconstruction.

6. COMPARISON OF CHARACTERISTICS:

The Innovasive 10mm LinX HT utilizes the same basic design for fixation into bone as the currently marketed 8mm LinX HT (K970316). This design utilizes a **central pin** placed inside an **outer sleeve** resulting in the expansion of the outer sleeve and the ultimate fixation of the device into bone.

7. PERFORMANCE DATA:

The following performance data was provided in support of the substantial equivalence determination:

1. Mechanical Testing: Comparison of the ultimate holding strength in a bone model compared to the predicate device. The Innovasive 10mm LinX HT holding strength was found to be equivalent to the strength of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 1998

Mr. Stephen M. Page
Manager of Regulatory Affairs
Innovasive Devices, Inc.
734 Forest Street
Marlborough, Massachusetts 01752

Re: K980334
Trade Name: Innovasive 10mm LinX HT Ligament Fastener
Regulatory Class: MBI and HRX
Product Code: II
Dated: January 26, 1998
Received: January 28, 1998

Dear Mr. Page:

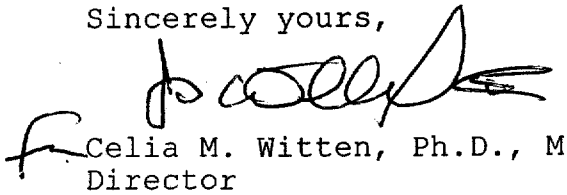
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K980334

INDICATIONS FOR USE
10mm LinX HT

The 10mm LinX HT is intended for use in the fixation of ligament and tendon grafts in cruciate ligament reconstruction surgeries.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980334